Cotronic Manufacturing
Floor 4-6, Block 7, West of Zhoushi Road, Xixiang Street, BaoAn zone,
ShenZhen, Guang Dong, P.R. China

K103407|S1

510K Summary

510(K)#103407

MAY 13 2011

Date: October 16, 2010

U.S. Agent and Primary Contact

Yan Dur Lin
Abertek Company
23 Josiah Ave
San Francisco, CA 94112
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510K Holder

Cotronic Manufacturing
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Manufacturer

Cotronic Manufacturing
F4 Block4, FuYuan Ind Zone, JiuWei, XiXiang,
BaoAn Zone, ShenZhen, GuangDong, P. R. China
+86 755-81453681-1030
Owner/Opeartor Number: 9057884
FDA Registration Number: 3004215929

Device Information

Trade Name:	Clinical Electronic Thermometer
Model:	TM12 and TM21
Common Name:	Oral Thermometer
Classification Name:	Thermometer, Clinical, Electronic
Class:	II
Regulation:	880.291
Product Code:	FLL – Clinical Electronic Thermometer

Device Description

The clinical electronic thermometer is used over the counter to measure the human body temperature orally, auxiliary, and through the rectum. The device has the following skin contact parts: stainless steel tip, ABS plastic housing, and Ethylene/Butylene-Styrene Block thermoplastic housing. The method used to measure the temperature of a human follows the standard ASTM E1112(Standard Specifications for Electronic Thermometer for Intermittent Determination of Patient Temperature).

Performance Summary

The device follows the following standards: ASTM E1112, IEC60601-1, and IEC60601-1-2. The device meets Biocompatibility Standards for ISO 10993-5:2009(E), EPA Nitro-amines - USA 21 CFR Part 58, ISO 10993-10:2002/Amd.1:2006, idt EN10993-10:2009, and ISO 10993-12:2007 Bioevaluation.

Predicate Device

Cotronic Clinical Electronic Thermometer, Model TM01 and TM02.

Conclusion

The Clinical Electronic Thermometer, TM12 and TM21, is substantially equivalent to the legally marketed device by Cotronic's Clinical Electronic Thermometer, TM01 and TM02, any difference in their technological characteristics that do exist would not have a significant effect on the safety or effectiveness of the device. TM12 and TM21 are substantially equivalent to the predicate devices, TM01 and TM02.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 13 2011

Cotronic Manufacturing
C/O Mr. Yan Dur Lin
General Manager and Owner
Abertek
23 Josiah Avenue
San Francisco, California 94112

Re: K103407
Trade/Device Name: Cotronic Digital Thermometer
Regulation Number: 21 CFR 80.2910
Regulation Name: Thermometer, Clinical Electronic
Regulatory Class: II
Product Code: FLL
Dated: October 16, 2011
Received: April 19, 2011

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Cotronic Manufacturing
Floor 4-6, Block 7, West of Zhoushi Road, Xixiang Street, BaoAn zone,
ShenZhen, Guang Dong, P.R. China

Indications for Use

Clinical Electronic Thermometer Model TM12 and TM21

This clinical electronic thermometer is used over the counter to measure the human body temperature orally, auxiliary, and through the rectum.

Prescription Use_____ AND/OR Over-The-Counter-Use X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Lydia for RZC May 13, 2011
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103407